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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,476	12/05/2005	Guillermo Selman-Housein Sosa	976-26 PCT/US	4933

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HOFFMANN & BARON, LLP  
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EXAMINER
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HIBBERT, CATHERINE S

ART UNIT	PAPER NUMBER
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1636

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01/10/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/539,476

Applicant(s)

SOSA ET AL.

Examiner

Catherine S. Hibbert

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-72 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-72 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

Claims 1-72 are pending.

#### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-31, 55 and claim 57, drawn to an artificial promoter, a cassette and a vector.

Group II, claim(s) 32-54, 56, and claim 57, drawn to a DNA fragment from an artificial promoter, a cassette and a vector.

Group III, claim(s) claim 58, drawn to a bacterial cell.

Group IV, claim(s) 59-61, and claims 71-72, drawn to a plant cell and use of recombinant proteins produced.

Group V, claim(s) 62-70, and claims 71-72, drawn to a transgenic plant(s) and use of recombinant proteins produced.

The inventions listed as Groups I- VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Initially, it is noted that the claimed artificial promoter comprising a synthetic nucleotide of an Exon/Intron/Exon does not represent an advance over the art [see WO/91/09948 (11 July 1991) or WO/99/43838 (2 September 1999), cited in search report) and hence there is no unity of invention..

The technical feature of Group I is an artificial promoter. Each of the other Groups is characterized by a technical feature which defines an advance over that of Group I. The technical feature of Group II is a DNA fragment of an artificial promoter and as such represents a different polynucleotide molecule than that of Group I which has different secondary and tertiary structure. The technical feature of Group III is a bacterial cell carrying a vector. The technical feature of the Group IV is a plant cell(s) carrying a vector. Groups III and IV are mutually exclusive. The technical feature of Group V is a transgenic plant. The compositions of Groups I-V are distinct as each is defined by distinct features, i.e. nucleic acids molecules versus cells, and a plant cell versus a transgenic plant. The compositions of Groups I-V can be used in different methods.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance

with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

### ***Species Election***

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

This application contains claims directed to the following patentably distinct species:

**-If Applicant elects Group I, Applicant must further elect:**

**-only one type of 5' transcription regulation element** (or one combination of regulator elements operatively fused, claim 22) from between "artificial" (claim 2) and "homologous to a DNA sequence that naturally enhances and/or regulates gene expression in plant cells" (claim 3).

**-Furthermore, if Applicant elects the type "artificial" (claim 2),**

**Applicant must further elect:**

**-only one type of element** from between wherein the element is an *as-1*-like transcriptional enhancer (claim 11)

and wherein the element is from the rice gluteline B-1 gene (claim 17).

**-only one type** of control of gene expression from among developmental, organ-specificity, tissue-specificity, expression in seeds, in plant cells under biotic stress, in plant cells under abiotic stress, and in wounded plant tissue (claims 15, 16, 20 and 21).

**-Furthermore**, if Applicant elects the type "homologous to a DNA sequence that naturally enhances and/or regulates gene expression in plant cells" (claim 3), Applicant must further elect:

**-only one type** of element from among rice; maize and viral (claims 4, 8 and 13).

**-Furthermore**, if Applicant elects rice (claim 4), Applicant must further elect only one type from between SEQ ID NO:10 and SEQ ID NO:11 (claims 6 and 7).

**-only one type of first Exon** from between those in claims 23 and 24.

**-only one type of second Exon** from between those in claims 27 and 28.

**-only one type of Exon/Intron/Exon region** from among SEQ ID NO:s 6, 8 and 20 (claims 26 and 30-31).

**-If Applicant elects Groups I, II, III, IV or V**, Applicant must further elect:



**-only one type of DNA vector** from between “for the expression of DNA sequences in plant cells containing an artificial promoter responding to claim 1” and “for the expression of DNA sequences in plant cells containing a transcription enhancer element functionally fused to a DNA fragment from an artificial promoter according to claim 1 such that , when fused to a promoter functional in plants, contributes to enhanced expression of DNA sequences controlled by said promoter” (claim 57).

**Examiner’s note: Claim 57 requires an election of species whereby the species pertain to two patentably distinct inventions. Applicant must elect the species “for the expression of DNA sequences in plant cells containing an artificial promoter responding to claim 1” if Applicant elects Group I and Applicant must elect the species “for the expression of DNA sequences in plant cells containing a transcription enhancer element functionally fused to a DNA fragment from an artificial promoter according to claim 1 such that , when fused to a promoter functional in plants, contributes to enhanced expression of DNA sequences controlled by said promoter” if Applicant elects Group II.**

**-If Applicant elects Group II, Applicant must further elect:**

**-only one type of DNA fragment sequence corresponding to only one SEQ ID NO. from those listed in claims 32-54.**

**-If Applicant elects Groups IV or V, Applicant must further elect:**

-either "artificial promoter" or "DNA fragments" under the control of an artificial promoter (claims 71 and 72).

-either cells or plants (claims 71 and 72).

**Examiner's note: Claims 71 and 72 require an election of species whereby the species pertain to two patentably distinct inventions. Applicant must elect the species "cells" if Applicant elects Group IV and Applicant must elect the species "plants" if Applicant elects Group V.**

**-If Applicant elects Group V, Applicant must further elect:**

**-between dicots and monocots (claims 65 and 68).**

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the reasons given above.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or

employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the

prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Hibbert, Ph.D., whose telephone number is 571-270-3053. The examiner can normally be reached on Monday-Friday, 7:30 AM-5:00 PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D., can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patent Examiner: Catherine S. Hibbert

  
DAVID GUZO  
PRIMARY EXAMINER